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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,940	02/12/2001	Donald R. Ricci	213202.00195	1694

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

41

Office Action Summary	Application No.	Applicant(s)	
	09/780,940	RICCI, DONALD R.	
	Examiner	Art Unit	
	Bruce E Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 4, 11-13, 16 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10, 14, 15 and 17-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> . | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Election/Restrictions

Claims 4, 11-13, 16, 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7. Applicant's traversal is on the grounds that it does not burden the search. The separate inventions present an added burden to the Office in prosecution as well as searching for all embodiments. It is the Examiner's position that the embodiments are patentably distinct and are correctly separated.

Claims 11-13, 16, and 22 are withdrawn according to applicant.

Claim 4 is further withdrawn because referring to the elected figure 15, the slit 235a clearly fails to extend to a distal opening forward of the balloon or even opening 250.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 recites the limitation "second pair" in line 2. There is insufficient antecedent basis for this limitation in the claim. The claim is ambiguous.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 6 is not understood. Referring to elected figure 15, no valve is shown, no second slit is shown, third lumen is not understood. Also, how are the second and third lumen in communication?

Claim 7 is not understood. Please direct to figures and specification for support.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's application does not support "a semi-circular shaped cross-section".

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, claims 6-7 including a valve etc. must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

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A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 6, including a valve is not supported in the specification.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: first lumen, second lumen, second pair, third lumen etc. are not supported. It is applicant's responsibility to check all claim terminology for supported.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 5-10, 14-15, 17-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Johnson et al (5,205,822).

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Johnson et al teaches a balloon catheter comprising a tubular member 16; an inflatable balloon 12; first lumen 18; second lumen 20 for receiving a guidewire having a first proximal opening and a second distal opening (see figure 1, element 20); first slit 28 having a pair of longitudinal side edges which allow for removal of the guidewire, therefore, inherently meets all functional language.

See adapter 14.

Regarding a valve, it is inherent with a balloon catheter having a guide wire.

Regarding claim 14, Johnson et al teaches a second lumen 20 having a circular cross-section. The first lumen 18 has a truncated circular cross-section wherein circular portion is greater than half; the cross-section is therefore interpreted as a "substantially" circular cross-section.

Claims 1-3, 5-10, 14-15, 17-20 are rejected under 35 U.S.C. 102(b) as being **clearly anticipated** by Gharibadeh et al (5,458,613).

Gharibadeh et al teaches a balloon catheter comprising a tubular member 10; an inflatable balloon 13; first lumen 12; second lumen 14 for receiving a guidewire having a first proximal opening and a second distal opening; first slit 24 has a pair of longitudinal side edges which allow for removal of the guidewire; ramp 41; port 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (5,205,822).

Johnson et al teaches a balloon catheter and guide wire as described above, however, does not teach a guide catheter. It would have been obvious to one having ordinary skill in the art to combine the catheter of Johnson et al and a guide catheter for procedures necessitating a guide catheter, such as to protect the balloon catheter and stent combination during implantation.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (5,205,822) in view of Applicant's specification.

Johnson et al teaches a balloon catheter as described above, however, does not teach a stent in combination with said catheter. Applicant's specification, page 1, lines 9-10, teach *"in recent years, balloon dilation catheters have also been used to facilitate delivery of endovascular prosthesis' such as stents."* It would have been obvious to one having ordinary skill in the art to combine the catheter of Johnson et al and stent as taught by applicant for all the known reasoning of utilizing a stent.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gharibadeh et al (5,458,613) in view of Applicant's specification.

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Gharibadeh et al teaches a balloon catheter as described above, however, does not teach a stent in combination with said catheter. Applicant's specification, page 1, lines 9-10, teach "*in recent years, balloon dilation catheters have also been used to facilitate delivery of endovascular prosthesis' such as stents.*" It would have been obvious to one having ordinary skill in the art to combine the catheter of Gharibadeh et al and stent as taught by applicant for all the known reasoning of utilizing a stent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

bes
February 11, 2003

A handwritten signature in black ink, appearing to be 'BSN' with a long horizontal stroke extending to the right.

**BRUCE SNOW
PRIMARY EXAMINER**